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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,791	12/27/2001	Jinn-Chu Chen	MR2723-138	9290

4586 7590 05/10/2004

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,791	CHEN ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment filed 4/23/04 is acknowledged. Claims 10-12 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for polysaccharides having a molecular weight in the range of 500,000 to 2,000,200. To begin with, the specification indicates that the composition **"may contain"** this material, not that it contains it. Moreover, there is no clear indication of the source of the figure "2,000,200". The specification mentions $200 \times 10^{4.}$

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 12 are vague and indefinite in the recitation "derived from", since it is unclear whether the biologically active material is derived by chemical, physical or biological means. Amendment to -- obtained from-- would be remedial.

Claim 12 is confusing in the phrase "stimulates lymphocytic increase". The term "lymphocytic" is unknown.

The recitation of "the cytokine of Th1-type" and "the cytokine of Th2-type" renders the claim confusing, since the cytokine(s) intended are not clearly delineated or defined. The metes and bounds of "the cytokine of Th1-type" and "the cytokine of Th2-type" in this context cannot be readily determined. No clear definition is provided in the as filed specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Li *et al.* or Huang *et al.* (of record) in light of Hseu *et al.* and Wu *et al.*.

The claims are directed to a biologically active material derived from *A. camphorata* mycelium containing polysaccharides.

Each of the references Li *et al.* and Huang *et al.* discloses biologically active material obtained from *A. camphorata* which inherently contains the required derived compositions comprising polysaccharides either derived as a part of the mycelium compositions or derived as part of the culture medium material containing substances such as polysaccharides secreted into the culture medium. See, e.g., Li *et al.*, Example 4; See, e.g. Huang example 3. It is noted that at least the compositions of Huang *et al.* have antitumor activity, which appears to be the activity as claimed in claim 12. Hseu *et al.* is cited as evidence of the high polysaccharide content of *Ganoderma* species (See, e.g., Abstract), and Wu *et al.* is cited to demonstrate that *A. camphorata* is conspecific with *Ganoderma camphoratum* (See, e.g., page 273, col. 2).

Therefore, the invention as claimed is anticipated by the references.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that the Li reference differs from the claimed invention in the use of solid state fermentation. However, the claims are not directed to a fermentation process but rather to a product-by-process, wherein the product is examined.

With regard to the alleged "significant" polysaccharide content, the present specification does not provide a positive recitation regarding the polysaccharides content and its molecular weight. The specification indicates that the composition **"may contain"** this material, not that it contains it. Applicants appear to argue that the amount of biologically active material is different because it is a "significant" amount. However, the precise amount encompassed by "significant" is not clearly delineated in the written disclosure and does not in itself patentably distinguish over the prior art compositions. Regarding the identification of the polysaccharides produced in the specification, applicants have not conducted an analysis of the product produced by the actual strain of *A. camphorata* cultured, i.e., CCRC 35398 . It cannot readily be determined whether the process *per se,* with respect to media and/or culturing conditions, for example, or the strain cultured are responsible for the alleged superior results. Also it is unclear whether the strain CCRC 35398 used in the disclosed process is publicly available from a recognized depository.

Regarding the Huang patent, applicant argues that the instant product and method are related to a product produced by fermenting, freezing and then drying of mycelium, while the product produced by the reference differs in these respects. However, this argument is not persuasive because it does not pertain to the claim designated invention.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' product obtained by culturing *A. camphorata* differs and, if so, to what extent, from the product discussed in the references. Accordingly, inasmuch as the examiner has established that the prior art product, which is produced by a strain of the same species *A. camphorata* as that claimed, likewise shares the property of being able to produce metabolites having pharmaceutical and medicinal activities, in particular being inhibitory towards tumor cells, she has reasonably demonstrated a reasonable likelihood/possibility that the compared compositions are either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing anticipation/non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651